

Appl. No. 09/529,575  
Amdt. Dated March 23, 2004  
Reply to Office Action of Dec. 23, 2003

#### REMARKS

Claims 31-33, 36, 41-46, and 48-53 are pending in the present application and stand rejected.

Claim 31 has been amended to recite "and wherein an extract of at least a portion of the article produces at least a 10% reduction in substrate hydrolysis by a protease in an Absorbent Article Test Method and the article." Support for this amendment may be found at page 26, lines 16-22.

Claim 33 has been cancelled without prejudice.

Claim 36 has been amended to recite a preferred embodiment dependent from Claim 31. Support for this amendment may be found at page 26, lines 16-22.

No new matter has been added, and, as a result, entry is respectfully requested.

#### REJECTIONS UNDER 35 USC § 103(a)

Applicants respectfully submit that the Office has failed to make a *prima facie* case for the obviousness rejections presented below. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. See *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992); MPEP § 2143.01. Second, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); MPEP § 2143.02. Third, the prior art reference or combined references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981 (CCPA 1974); MPEP § 2143.03. Furthermore, in establishing a *prima facie* of obviousness, case law clearly places the "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967). Applicants traverse each rejection.

Claims 31-33, 36, 41-46, and 48-53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable U.S. Patent No. 5,874,164 to Caldwell (hereinafter "Caldwell"). With respect to Claims 31-33, 36, 41-44, 48, 49, 51, and 52, the Office states that Caldwell discloses an absorbent article at least a portion of which comprises a protease inhibitor. The Office states the "protease inhibitor is pentamidine . . . which has an IC<sub>50</sub> of about 500 μM or less, no more than 100 μM, and produces at least a 10% reduction in substrate hydrolysis by a protease." The Office concludes that "it would have been obvious to one of ordinary skill in the art at the time of invention to have protease inhibitor present in the amounts of between 0.0001% and about 30% by weight, since it has been held that where the general conditions of a claim . . . are disclosed in the art, discovering the optimum or workable ranges involves only routine skill in the art." Applicants traverse this rejection.

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Applicants submit that the claims are not rendered obvious in view of Caldwell. Caldwell teaches barrier fabrics that are substantially impermeable to water, substantially permeable to gases and impermeable or selectively impermeable to particles such as microorganisms, cells, and the like. *See Abstract*. Caldwell discloses that garments can be made using the barrier fabric. Col. 52, line 59 – Col. 53, line 7. Caldwell further discloses that “the present invention includes the incorporation of other antimicrobial agents, including antifungal agents, antiviral agents, and antiparasitic agents. Examples include, but are not limited to isoniazid, ethambutol, pyrazinamide, streptomycin, clofazimine, rifabutin, fluoroquinolones, ofloxacin, sparfloxacin, rifampin, azithromycin, clarithromycin, fluoroquinolones, dapsone, tetracycline, doxycycline, erythromycin, ciprofloxacin, doxycycline, ampicillin, amphotericin B, ketoconazole, fluconazole, pyrimethamine, sulfadiazine, clindamycin, lincomycin, azithromycin, clarithromycin, pentamidine, atovaquone, paromomycin, diclazaril, acyclovir, trifluorouridine, foscarnet, and ganciclovir.” Col. 55, line 16-30.

With regard to Claim 31 as amended, the Office has failed to establish a *prima facie* case of obviousness because the reference fails to teach or suggest at least three of Applicants’ claim limitations.

First, Caldwell does not teach or suggest the concentration of protease inhibitors. Caldwell merely discloses that pentamidine is one of many antimicrobial agents. The Office concludes that “it would have been obvious to one of ordinary skill in the art at the time of invention to have protease inhibitor present in the amounts of between 0.0001% and about 30% by weight, since it has been held that where the general conditions of a claim . . . are disclosed in the art, discovering the optimum or workable ranges involves only routine skill in the art.” The Office cites *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955) as support for its conclusion. However, the Office has failed to consider the full text of MPEP § 2144.05 and the case law cited therein. For example, “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable that achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” MPEP 2144.05; *See In re Antonie*, 559 F.2d 618 (CCPA 1977). The Office has failed to point to a teaching within Caldwell that recognizes that the amount of pentamidine is a “results-effective variable.” The Office’s assertion that it is obvious to discover optimum or workable ranges is without merit absent some showing that pentamidine is a variable that achieves a recognized result.

Second, Caldwell does not teach or suggest a protease inhibitor having an  $IC_{50}$  of about 500  $\mu$ M or less. The Office states that “[t]he protease inhibitor is pentamidine, as described in column 55, line 28, which has an  $IC_{50}$  of about 500  $\mu$ M less, no more than 100  $\mu$ M, and produces

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at least a 10% reduction in substrate hydrolysis by a protease." However, Caldwell fails to teach or suggest  $IC_{50}$  values. The citation provided by the Office lists pentamidine as one of 37 possible antimicrobials for use in the barrier web of Caldwell. No disclosure is made as to  $IC_{50}$ . As a result, the Office has failed to teach or suggest all of Applicants' claim limitations.

Regarding the  $IC_{50}$  values, the Office in past Office Actions (e.g., Paper No. 14 dated June 7, 2002) has considered  $IC_{50}$  to be an inherent property in the protease inhibitor itself. Such reasoning is inapplicable here because the doctrine of inherency has no place in the determination of obviousness. Case law has held: "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d 444, 448 (CCPA 1966). Caldwell fails to disclose or suggest that pentamidine is a protease inhibitor and the Office points to no reference teaching or suggesting that pentamidine is a protease inhibitor. Furthermore, Caldwell fails to disclose or suggest  $IC_{50}$  values and the Office points to no reference teaching or suggesting  $IC_{50}$  values. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983). The Office appears to have engaged in impermissible hindsight reconstruction since nothing other than Applicants' disclosure teaches or suggests the  $IC_{50}$  values.

Third, Claim 31 has been amended to recite "wherein an extract of at least a portion of the article produces at least a 10% reduction in substrate hydrolysis by a protease in an Absorbent Article Test Method." As previously stated, the Office asserts that Caldwell teaches that "[t]he protease inhibitor is pentamidine, as described in column 55, line 28, which . . . produces at least a 10% reduction in substrate hydrolysis by a protease." However, Caldwell fails to teach or suggest a 10% reduction in substrate hydrolysis. Nothing in Caldwell teaches an article producing a reduction in substrate hydrolysis as claimed by Applicants. Furthermore, since this is an obviousness rejection, the Office may not resort to inherency. As a result, the Office has failed to teach or suggest all of Applicants' claim limitations.

Claims 32, 36, 41-47, and 48-53 depend from and contain all the limitations of Claim 31. Since Claim 31 is nonobvious in light of the arguments presented above, the claims dependent therefrom are also nonobvious.

Regarding Claim 32, the reference cited by the Office fails to teach all the claim limitations. Applicants recite the limitation "wherein the  $IC_{50}$  is no more than 100  $\mu$ M." As presented above, Applicants have shown that Caldwell fails to teach or suggest an  $IC_{50}$  of about 500  $\mu$ M. Likewise, the same reasoning applies with regard to the limitation where the  $IC_{50}$  is

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more than 100  $\mu$ M.

Regarding Claim 36, the reference cited by the Office fails to teach all the claim limitations. Applicants recite the limitation "wherein the article produces a 20% reduction in substrate hydrolysis by a protease in an Absorbent Article Test Method." As presented above, Applicants have shown that Caldwell fails to teach or suggest an article that produces a 10% reduction in substrate hydrolysis by protease. Likewise, the same reasoning applies with regard to the limitation where the article produces a 20% reduction in substrate hydrolysis by a protease.

Regarding Claim 42, the reference cited by the Office fails to teach all the claim limitations. Claim 42, which depends from Claim 41 which itself is dependent from Claim 31, discloses an absorbent article which comprises a delivery system as a skin care composition which comprises about 0.01% to 50% by weight protease inhibitor. The Office asserts that "the article [of Caldwell] can comprise a delivery system, a bandage or surgical gauze . . . which facilitates the healing of wounds and is therefore a skin care composition." If the delivery system is a bandage or gauze, Applicants' are unclear as to what the Office believes is the absorbent article. The bandage or gauze can not be the absorbent article because the Office has already asserted that it is the delivery system. Applicants will not speculate on what the Office intended; however, the Office has failed to teach or suggest all of Applicants' claim limitations.

Regarding Claim 45, the reference cited by the Office fails to teach or suggest all the claim limitations. Claim 45 recites that the "delivery system is activatable by moisture, heat, or pressure, or a combination thereof." The Office asserts that column 55, lines 31-35 disclose this limitations. However, Caldwell does not disclose moisture, heat, or pressure activation. Caldwell discloses, "It is to be understood that the antimicrobial agent can be incorporated into the polymer so that the agent is released over a period of time. In this way, the barrier web retains its ability to kill or inhibit microorganisms over a long period of time." Clearly Caldwell does not teach or suggest a delivery system activatable by moisture, heat, pressure, or a combination.

Regarding Claim 46, the reference cited by the Office fails to teach or suggest all the claim limitations. Claim 46 recites that the "delivery system contains the protease inhibitor as a powder, a flake, a particle, a solution, a suspension, a dispersion, an emulsion, or combination thereof." The Office asserts that Caldwell's disclosure of "antimicrobial molecules" teaches Applicants' protease inhibitor as a particle. Applicants again submit that to establish a *prima facie* of obviousness, the Office must initially produce the factual basis for its rejection of an application under sections 102 and 103." See *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967). Applicants submit that the Office has provided no support, factual or otherwise, to suggest that molecule discloses Applicants' limitation of "particle."

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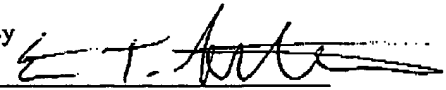
**CONCLUSION**

Based on the foregoing reasons, Applicants respectfully submit that the Office has not made a *prima facie* case of obviousness and the rejections are therefore improper. Reconsideration and withdrawal of the rejections are respectfully requested. Allowance of each of the pending claims in the next Office Action is respectfully requested.

Respectfully Submitted,

For: F.J. Rourke et al.

By



Eric T. Addington  
Attorney for Applicants  
Registration No. 52,403

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Customer No. 27752